Cavanagh, James

As a radiologist practicing breast imaging for the past 20 years I have been actively involved in improving quality of breast imaging studies and increasing sensitivity for breast cancer detection. Along with my colleagues I have worked with the American College of Radiology to ensure access to high quality mammography, breast ultrasound and breast magnetic resonance imaging (MRI) for the women of Michigan.

Mammographic screening has dramatically reduced breast cancer deaths (30% reduction in breast cancer deaths since 1990), but does not depict all cancer early enough to result in cure. Other modalities, including whole breast ultrasound and breast MRI, have been evaluated to increase cancer detection but none to date have shown the sensitivity required to eliminate late stage cancer diagnosis. Also, screening whole breast ultrasound has the added disadvantage of many false positive findings resulting in unnecessary biopsy. In published studies the false positive rate for biopsies performed because of abnormalities found on screening breast ultrasound ranges from 84 to 94.5% (1,2,3). Despite the high number of biopsies performed as a result of screening breast ultrasound, there are a significant number of cancers that are undetectable with screening breast ultrasound. The ACRIN 6666 trial demonstrated that mammography detected more cancer than screening breast ultrasound.(3)

Breast Ultrasound is an invaluable tool for characterizing masses found with mammography or on physical exam. The success of breast ultrasound as a diagnostic tool has led many to believe that it should also be a good screening tool, but this has not been proven. Two studies have been published since breast density legislation was passed in Connecticut in 2009. A multicenter retrospective trial of 8647 screening breast ultrasound exams in women with dense breasts over a one year period demonstrated a low cancer detection rate of 3.2 cancers per 1000 exams. 418 biopsies were performed to detect 28 cancers, with a positive predictive value of 6.7%. (1) By comparison the positive predictive value of mammography in the US is 20 to 40%. The average cost per biopsy was reported as $2400, totaling an almost one million dollar cost for unnecessary biopsies. The second study of 5519 screening breast ultrasound examinations for women with dense breasts demonstrated an even poorer cancer detection rate of 1.8 per 1000 exams and a positive predictive value of 5.5%. (2) My objections to HB 4260 are as follows:

1. The proposed legislation suggests women with dense breasts should undergo additional screening for breast cancer with ultrasound even though it has been proven that additional screening breast ultrasound results in many unnecessary biopsies and is not as good as mammography for detecting breast cancer. We in Michigan have the benefit of evaluating results of screening ultrasound in Connecticut and should realize screening breast ultrasound is not the "sure thing" we had hoped it would be.

2. HB 4260 lags behind scientific innovation and improved cancer detection methods. Digital Breast Tomosynthesis (DBT) is an advancement in digital mammography that offers improved detection of breast cancer and a lower false positive rate than traditional digital mammography.(4) Studies are underway to prove the benefit of DBT for all women undergoing screening, not just those with dense breasts.

3. HB 4260 exaggerates the risk breast density adds to a women's lifetime risk of breast cancer which may be as low as 1.2 times average risk. Other risk factors such as family history, alcohol consumption and obesity are greater contributors to breast cancer risk than breast density. Scientific investigation is moving forward to identify those at greatest risk. This bill lags far behind the latest investigations and is a disservice to women as it focus attention away from the most important risk factors.(4)

4. Measurement of breast density is subjective, based on the training and experience of the radiologist interpreting a mammogram. A woman can be assigned to the heterogeneously dense category by one reader and a scattered density category by another reader.

I have devoted my career to detecting early stage, curable, breast cancer. If HB4260 contributed significantly to early breast cancer detection, I would be behind it 100%, but it does not. I ask you Representative Haines, to do your best not to subject women to this legislation.

I have attached a copy of the Michigan Cancer Consortium information letter regarding breast density and the references I cited above.

Best Regards,
Trish Miller

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References important to breast density legislation.

1. Weigert , et al; The Connecticut Experiment: The Role of Ultrasound in Screening of Women with Dense Breasts. The Breast Journal Vol 18, Number 6, 2012 517-522.
2. Parris et al; Real World Performance of Screening Breast Ultrasound Following Enactment of Connecticut Bill 458. The Breast Journal Vol 19, Number 1, 2013 64-70.
3. Berg WA et al; Detection of breast cancer with addition of annual screening ultrasound or a single screening MRI to mammography in women with elevated breast cancer risk. JAMA. 2012;307:1394-1404.
4. Kopans, DB; Digital Breast Tomosynthesis from Concept to Clinical Care. American Journal of Roentgenology. 2014;202:299-308.
5. Pinsky RW, Helvie, MA. Mammographic Breast Density: Effect on Imaging and Breast Cancer Risk. JNCCN. 2010; Vol 8, No10. 1157-1164.
6. Nicholson, Brandi T., et al. Accuracy of Assigned BI-RADS Breast Density Category Definitions. Acad Radiol 2006; 13: 1143-1149.

Michigan Cancer Consortium

Frequently Asked Questions about Breast Density and Breast Cancer Risk

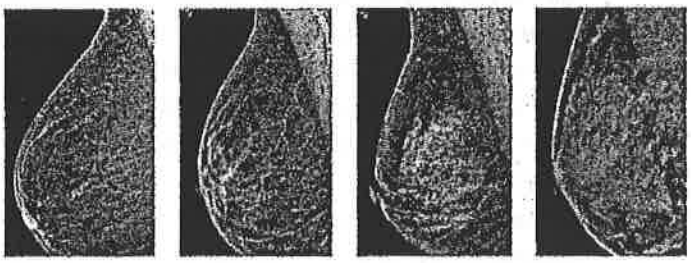
July 2013

What is Breast Density?

Breast density is defined as the ratio of fat to fibroglandular tissue in the breast.

Radiologists characterize each mammogram into one of four levels of overall density: almost entirely fatty, scattered areas of fibroglandular density, heterogeneously dense, and extremely dense.

Radiologists classify breast density using a 4-level density scale:



Almost entirely fatty | Scattered areas of fibroglandular density | Heterogeneously dense | Extremely dense

What is the significance of mammographic breast density?

There are two primary implications of mammographic breast density.

1. The first involves the effect on mammographic sensitivity (i.e. the test's ability to identify a clinically occult malignancy, known as "masking").
   - Masking occurs when surrounding breast tissue obscures a cancer. The cancer is not discernible on a mammogram, limiting the sensitivity of the screening test.
   - The sensitivity of mammography is reduced as background breast tissue density increases. When mammography is the only screening test performed, sensitivity decreases by 10% to 20% for women with "dense breasts".

2. The second involves the increase in breast cancer risk imparted by dense breasts.
   - Overall, the potential masking effect of breast density is likely of greater import than the minor increase in breast cancer risk.

How high is the cancer risk associated with breast density?

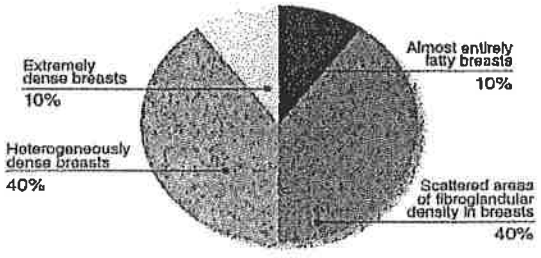
The medical literature on the impact of density on this cancer risk is often misleading because most studies describe the risk by comparing the 10% of women in the highest density category (extremely dense) with the 10% of women in the lowest density category (almost entirely fatty). This is not meaningful to the other 80% of women, nor should risk comparisons be related to such a small subset of the patient population.

When risk is expressed relative to average breast density (between scattered areas of fibroglandular density and heterogeneously dense),

- The cancer risk for the 40% of women with heterogeneously dense breasts is only about 1.2 times greater than women with non-dense breasts and
- The risk for the 10% of women with extremely dense breasts is only about 2 times greater than women with non dense breasts.
- Therefore, breast density is not a major cancer risk.

Breast density in the U.S. (See pie chart)

- 10% of women have almost entirely fatty breasts
- 10% have extremely dense breasts
- 80% are classified into one of two middle categories



Should a woman with dense breasts still get a mammogram?

Yes. Mammography is the only screening tool that has been demonstrated through large randomized trials to lower breast cancer mortality. Those trials included all breast densities. While mammography sensitivity is somewhat lower in women with extremely dense breasts, it is still the best modality for population-based screening. Also, mammography is the only test that can reliably detect suspicious calcifications. Such calcifications are often the first sign of in-situ cancers, which (in 20% of cases), coexist with otherwise invisible invasive cancers.

There is no recommendation that mammography be replaced with another test in any subset of the population.

The American Cancer Society, American College of Radiology, Society of Breast Imaging and American College of Obstetricians and Gynecologists, among others, recommend that all women have yearly mammograms beginning at age 40.

For women with dense breasts, what additional options are available?

For patients who are interested in additional screening options, a breast cancer risk assessment may be appropriate. Patients are encouraged to discuss with their provider and/or breast specialist whether supplemental tests and/or other interventions aimed at reducing breast cancer risk will be beneficial.

The issue of breast density provides a major impetus to the perceived need for additional breast cancer screening modality(s). Among the additional tests that are available, screening breast MRI and screening breast ultrasound have been tested extensively. Background breast density has less impact on the ability of MRI and ultrasound to detect cancer than it does for mammography, which is why each of these tests increases cancer detection over mammography alone, MRI much more so than ultrasound. However, both MRI and ultrasound are associated with a much higher rate of benign biopsies and a much higher rate of recommendation for short-interval follow-up than mammography. Therefore, choosing to have one of these tests in addition to mammography involves the benefit/risk trade-off of early cancer detection versus increased false positives. The higher the cancer risk, the more likely there will be benefit, so the trade-off can be more favorable for high risk women than for average-risk women who simply have dense breasts.

Screening breast MRI has been shown to substantially increase the rate of cancer detection. It is recommended, along with mammography, in patients who are at very high risk (>20% lifetime risk of breast cancer) based on one of several accepted risk assessment tools that look at family history and other risk factors.

For patients at an "intermediate risk," (equivalent to a 15% to 20% lifetime risk) a patient-centered shared decision –making approach is recommended between the patient and her provider and/or breast specialist. These intermediate risk patients include those with a personal history of breast cancer, a prior biopsy diagnosis of lobular carcinoma in situ (LCIS), atypical lobular hyperplasia (ALH), or atypical ductal hyperplasia (ADH).

Screening breast ultrasound is not offered at many centers and may entail an out-of -pocket charge to patients. Small studies have shown a modest increase in cancer detection, but also a high rate of false positives resulting in benign biopsies. The choice to have this test should be made on an individual basis after a discussion of these risks, benefits, and costs.